K041546

JUN 2 3 2004

Section G: Summary

510(k) Summary

Prepared: March 31, 2004

Submitter:

Company Name:	Canon USA, Inc. (U.S. agent for Canon Inc.)
Company Address:	One Canon Plaza Lake Success, NY 11042
Contact Person:	Ms. Sheila Driscoll
Phone Number:	(516) 328-5602
Fax Number:	(516) 328-5169

Proposed Device:

Reason For 510(k):	New Model
Manufacturer:	Canon Inc.
Trade Name:	Canon
Model Name:	CF-60DSi
Classification Name:	86HKI, Ophthalmic cameras
FDA 510(k) #:	To be assigned

Predicate Device:

Manufacturer:	Canon Inc.
Trade Name:	Canon
Model Name:	CF-60UVi
Classification Name:	86HKI, Ophthalmic cameras
FDA 510(k) #:	K946058

Intended Use: CF-60DSi is intended to be used for taking digital images pictures of retina of human eye with a mydriatic.

Description Of Device: CF-60DSi is an improved model of CF-60UVi. The DIGITAL FUNDUS CAMERA CF-60DSi is used for taking digital images of retina of human eye without a mydriatic. Canon EOS Digital Camera is mounted with CF-60DSi, can be viewed immediately, making procedures more efficient and many different applications, such as telemedicine and electronic filing.

The CF-60DSi's intended use is the same as that of CF-60UVi. However, the differences in design are as follows:

- EOS digital camera can be attached to the main unit of CF-60DSi directly. But CF-60UVi cannot be attached without an adapter.
- ICG digital camera can be attached to the sub mount of CF-60DSi with the adapter. The analog or digital CCD camera can be attached to the sub mount of CF-60UVi with the adapter, and 35mm camera can be attached with the 35mm double adapter, and also Polaroid film unit can be attached without the adapter.
- While CF-60DSi has 2 variable powers (60/40 degree), CF-60UVi has 3 variable powers (60/40/30 degree).
- A data card cannot be used.

K041546

Section G: Summary

CF-60DSi is equivalent to CF-60UVi in the following respect:

- The optical components and alignment.
- The mechanical structures of the CF-60DSi are almost same as the CF-60UVi. Please refer to the CF-60DSi comparison table provided in this section.

Table of comparison

		CF-60UVi	CF-60DSi
PERFORMANCE	Angle of view	60/40/30°	60/40°
	Actual image size	φ29×22(on 35mm film) φ7.5×5.7(Type 1:on sensor array) φ4.9×3.7(Type 2:on sensor array) φ75×57(on Polaroid film)	Same(on monitor) Same No Applicable No Applicable
	Min. diameter of pupil required	φ5.5mm(60/40/30°) φ4.0mm(with S.P switch ON in 30°)	Same(60/40°) φ4.0mm(with S.P switch ON in 40°)
	Working distance(WD)	45mm	Same
	Focusing	By aligning the split lines	Same
	Data to be printed	Hand-written data	No Applicable
	Eye fixation lamp	External	Same
	Filter set	Automatic/Manual	Same
	Light source for photography	Max. 300WS	Same
	Image unit	EOS Digital Camera(with Adapter) CCD camera(with Adapter) 3CCD camera(with Adapter) 35mm film unit Polaroid film unit No Applicable	EOS Digital Camera No Applicable No Applicable No Applicable No Applicable ICG digital camera(with Adapter)
	Working range Vertical Forward and back Right and left Chin rest (vertically)	 38mm 70mm 120mm 65mm	 Same Same Same Same
	Panning	30° right or left	Same
	External dimensions Main unit Power control unit	 W320×D560×H565mm W225×D390×H520mm	 Same W225×D380×H485mm
	Weight Main unit Power control unit	 Approx.26kg Approx.30kg	 Approx.27kg Approx.27kg
Intended use		Taking picture of retina of human eye	Same
Energy	used	1000VA	Same
	delivered	No Applicable	Same
Target population		Ophthalmologist	Same
Physical safety		UL544	UL60601-1
Compliance with standards		UL544	UL60601-1
Biocompatibility		No Applicable	Same
Labeling	Packaging	Printed model name is changed	

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 3 2004

Canon, Inc.
c/o Glenn M. Luchen
Underwriters Laboratories, Inc.
1285 Walt Whitman Rd.
Melville, NY 11747

Re: K041546
Trade/Device Name: Digital Fundus Camera, Model CF-60DSi
Regulation Number: 21 CFR 886.1120
Regulation Name: Ophthalmic camera
Regulatory Class: Class II
Product Code: HKI
Dated: June 7, 2004
Received: June 9, 2004

Dear Mr. Luchen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications Statement

510(K)Number(if known): K041546

Device Name: CF-60DSi

Indications for Use:

DIGITAL FUNDUS CAMERA CF-60DSi is intended to be used for taking digital images of retina of human eye with a mydriatic.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHERT PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation(ODE)

Prescription Use ✓ OR Over-The-Counter Use _____

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devices

510(k) Number K041546